REMARKS

In the Office Action dated December 26, 2002, section 3, the Examiner indicated that Applicant did not distinctly and specifically point out the errors in the restriction requirement and therefore it has been treated as an election without traverse. In reviewing the prior Office Action dated October 21, 2002, it was an election requirement, rather than a restriction requirement, which election requirement was not traversed. Clarification is hereby requested regarding any restriction requirement.

The typographic errors of claims 2 and 13, noted in section 6 of the Office Action, have been fixed. The Examiner's finding of these typographical errors is greatly appreciated. Additional typographical errors in the specification have also been fixed.

The claims have been amended to more clearly describe the invention in that the health supplement composition is for improving memory and cognitive abilities and has a very high dosage of the phosphoester. This high dosage is not anticipated by or obvious in light of the prior art.

In section 7 of the Office Action, the Examiner rejected claims 1, 2, 4, 5, 9-11, 13, 14 and 21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,043,323. The '323 Patent is directed to a supplement for use in dermatology and ulcer applications. Inflammation, altered platelet aggregation and capillary fragility conditions are also noted in the '323 Patent. This Patent does not anticipate or suggest the use of the supplement for improving memory and cognitive abilities. Likewise, the dosage for the entire '323 Patent composition is only 1-500 mg (1 to 2 times per day), of which the phosphatidylcholine is only a portion.

In contrast, Applicant's invention is for improving memory and cognitive abilities, prevents or treats illnesses or conditions of "a condition requiring memory improvement, a condition requiring

cognitive improvement, AIDS-associated dementia, Alzheimer's disease, benign senile forgetfulness, Down's syndrome-associated dementia, Lewy body dementia, multi-infarct dementia, multiple sclerosis, Parkinson's disease-associated dementia, tardive dyskinesia, Wernicke-Korsikoff syndrome, and alcoholism-associated dementia." In addition, Applicant's dosage of the phosphoester, considered one of the most important ingredients in the composition, is at a substantially higher dosage, namely between 500 mg and 26.8 grams (see Applicant's charts for these ranges). The 500 mg is listed as a minimum daily dosage for one of several of the phosphoesters (see page 10, lines 48 and 49), and the 26.8 grams is the maximum range for all of the phosphoesters (see page 9, lines 35-38, [500 mg + 16 gm + 10,000 mg + 300 mg = 26.8 g].) Accordingly, it is believed that Applicant's claims, as amended, are allowable over the '323 Patent.

In section 8 of the Office Action, the Examiner rejected claims 1, 2, 4, 5, 9-14 and 21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,648,377. The '377 Patent is directed to a supplement for use in atherosclerosis and cancer. This Patent does not anticipate or suggest the use of the supplement for improving memory and cognitive abilities. Likewise, the dosage for the phosphatidylcholine in the '377 Patent is only in the 100 mg range.

In contrast, Applicant's invention is for improving memory and cognitive abilities, prevents or treats illnesses or conditions of "a condition requiring memory improvement, a condition requiring cognitive improvement, AIDS-associated dementia, Alzheimer's disease, benign senile forgetfulness, Down's syndrome-associated dementia, Lewy body dementia, multi-infarct dementia, multiple sclerosis, Parkinson's disease-associated dementia, tardive dyskinesia, Wernicke-Korsikoff syndrome, and alcoholism-associated dementia." In addition, Applicant's dosage of the phosphoester, considered one of the most important ingredients in the composition, is at a substantially higher dosage, namely between 500 mg and 26.8 grams. Accordingly, it is believed that Applicant's claims, as amended, are allowable over the '377 Patent.

In section 9 of the Office Action, the Examiner rejected claims 1, 2, 4, 5, 9-14 and 21 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,043,323, U.S. Patent No. 5,648,377 and Castleman (*The Healing Herbs*), specifically referring to barberry, ginseng, gotu kola and turmeric. The '323 and '377 Patents have been discussed above. Their deficiencies are not remedied by combining them together or in combination with *The Healing Herbs*.

Since *The Healing Herbs* is only directed to the antioxidant component of the present invention, it does not provide for any increased dosage in the phosphoester. And, as discussed previously for the '323 and '377 Patents, the dosages of the phosphoester are substantially less than in Applicant's invention.

The phosphoester, in the high dosages claimed, is considered one of the most important element of the invention. The oxidants are combined with the phosphoester to create a synergistic effect with the phosphoester. Various antioxidants are known in the prior art to assist with memory and cognitive abilities, while others are not known or not generally known for these purposes. In any event, it is important in the present invention to provide the antioxidant with the phosphoester to provide a more synergistic effect and to enhance the memory and cognitive abilities.

The Healing Herbs does not mention any uses of certain herbs for improving memory and cognitive abilities. For barberry, the uses listed are for diarrhea, constipation, antibiotic, immune stimulant, pinkeye, high blood pressure, anti-inflammatory (e.g. arthritis), liver function and jaundice. Gotu kola is listed as helping improve circulation in the legs and insomnia, treating wounds and psoriasis, skin rash and leprosy. Turmeric (curry) is known for as a cleansing and digestive aid, and treatment for fever, infections, dysentery, arthritis, jaundice, gall bladder and liver problems, stopping bleeding, treating chest congestion and menstrual discomforts, wound treatment, intestinal parasites, heart protection.

reducing cholesterol and preventing cancer. Barberry, gotu kola and turmeric are not known for improving memory or cognitive abilities. And, it is not known in the prior art to combine barberry, or gotu kola, or turmeric, or any other oxidant, with the high-dosage phosphoester of the present invention.

For ginseng, the listed uses are as an aphrodisiac, memory enhancement, learning, productivity, physical stamina, immune function, reducing blood cholesterol and sugar (glucose) and minimizing the ravages of stress, aging, radiation, alcohol, and narcotics, mental exhaustion from overwork, loss of appetite, indigestion, asthma, laryngitis, bronchitis, tuberculosis, invigorates the virile powers, promotes vitality and longevity, treatment of fever, inflammations, colds, coughs, respiratory problems, depression, menstrual difficulties, childbirth and immune stimulation, protecting the body against stress, radiation and various chemical toxins, and increasing general resistance, is an adaptogen, counteracts fatigue, counteracts the damage caused by physical and emotional stress, prevents depletion of stress-fighting hormones in the adrenal gland, anti-clotting effect to prevent heart attack, for diabetes, liver protection, cancer, and sex stimulant. Applicant acknowledges that ginseng is known in the prior art to help improve memory; however, it is not known in the prior art to combine ginseng (or any other oxidant) with a phosphoester, in the high dosages for the phosphoester claimed by Applicant.

The Examiner makes substantial mention of use of the prior compositions to treat heart disease. However, Applicant's claims are directed to enhancing memory and cognitive abilities. The title of the application is "*Neuroceutical for Improving Memory and Cognitive Abilities.*" This particular application is directed to and the claims are now limited to such uses, with the amendment provided to the claims.

The Examiner noted that the references do not specifically teach adding the ingredients in the amounts claimed by Applicant, but indicated that one would routinely optimize that amount. However, it is not obvious, nor would one attempt to optimize to the high ranges of the phosphoester claimed by

Applicant, namely 500 mg to 26.8 grams of phosphoester. These ranges are outside those to be considered by those skilled in the art, and they do produce a highly effective and unexpected result.

In light of the above and the amendments to the claims, it is believed that all of the claims are allowable over the prior art cited by the Examiner. A notice of allowance is respectfully requested. Should the Examiner have any comments, questions or suggestions relating to a speedy disposition of the application, he is invited to call the undersigned.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached paper is captioned, "Version with Markings to Show Changes Made."

A check for additional claim fees is attached. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

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Version with Markings to Show Changes Made

In the specification:

Please amend the specification as follows:

The paragraph beginning on page 3, line 21, and ending on page 4, line 4, shall read as follows:

One of the more important focuses of health supplements is the reduction of free radicals. Free radicals are associated with aging of the brain. (*See*, Halliwell, B., Gutteridge, J.M.C., "Free Radicals in Biology and Medicine" (3rd ed.), ([2000]1999) New York, Oxford University Press.) Oxidative injury to the nervous system has been documented in diseases such as AIDS-associated dementia, Alzheimer's disease, benign senile forgetfulness (pre-Alzheimer's disorder), Down's syndrome-associated dementia, Lewy body dementia, multi-infarct dementia, multiple sclerosis, Parkinson's disease-associated dementia, tardive dyskinesia, Wernicke-Korsakoff syndrome, and alcoholism-associated dementia. Indeed, oxidative injury may be the final common pathway leading to cell death. (*See*, Joaquin, A.M., et al., "Functional Decline in Aging and Disease: A Role for Apoptosis," Journal American Geriatrics Society, (2001), vol. 49, pp. 1234-1240.) Numerous studies have shown benefit from the use of antioxidants in many of these disorders. (*See*, Halliwell, B., Gutteridge, J.M.C., "Free Radicals in Biology and Medicine" (3rd ed.), ([2000]1999) New York, Oxford University Press.)

The paragraph on page 7, lines 4-15, shall read as follows:

Synergy and bioavailability are unique in this formulation. For example, citrus bioflavonoids are antioxidants which also synergistically increase absorption of synthetic vitamin C, helping to maintain sustained blood levels of vitamin C in the blood. Another example of a synergistic relationship is use of acetyl-L-carnitine, which works synergistically raising sustained levels of glutathione and co-enzyme Q10. Vitamin E actually diminishes the toxicity of riboflavin. (*See*, Free Radical Biology and Medicine [1998]1999;24, pp. 798-808.) It should be noted that not all vitamins or other components are capable of

synergistic relationships The present invention utilizes viable synergistic relationships of at least two components of the invention, preferably utilizing at least one antioxidant, to avoid toxicity, increase activity, or maintain desired component or other chemical levels. Betaine, bromelain, and papain are preferably added to help increase bowel absorption and thus bioavailability. Lutein and zeaxanthin are also preferably included, for their ability to specifically enhance the beneficial effects of beta carotene and vitamin A.

In the claims:

Amend the following claims:

1. A health supplement composition for mammals for improving memory and cognitive abilities comprising:

at least one phosphoester in a daily amount of between approximately 500 mg and approximately 26.8 g; and

at least one synergistic antioxidant combination, wherein said synergistic antioxidant combination comprises at least one antioxidant and at least one other composition component that has a synergistic relationship with said antioxidant;

wherein said use on mammals comprises prevention or treatment of illnesses or conditions selected from the group consisting of a condition requiring memory improvement, cognitive improvement, AIDS-associated dementia, Alzheimer's disease, benign senile forgetfulness, Down's syndrome-associated dementia, Lewy body dementia, multi-infarct dementia, multiple sclerosis, Parkinson's disease-associated dementia, tardive dyskinesia, Wernicke-Korsikoff syndrome, and alcoholism-associated dementia.

2. The composition of claim 1 wherein said at least one phosphoester is selected from the group consisting of [phoshatidylcholine]phosphatidylcholine, phosphatidylserine, phosphatidylethanolamine and phosphatidylinositol.

11. (Twice Amended) The composition of claim 2 wherein said phosphoester comprises a daily dosage of between approximately 0 mg and approximately 16,000 mg of phosphatidylcholine, between approximately 0 mg and approximately 300 mg of phosphatidylserine, between approximately 0 mg and approximately 500 mg of phosphatidylethanolamine, and between approximately 0 mg and approximately 10,000 mg of phosphatidylinositol, wherein at least one component in said composition is present in an amount greater than [0]500 mg.

12. (Twice Amended) The composition of claim 2 wherein said phosphoester comprises a daily dosage of between approximately 0 mg and approximately 1000 mg of phosphatidylcholine, between approximately 0 mg and approximately 100 mg of phosphatidylserine, between approximately 0 mg and approximately 200 mg of phosphatidylethanolamine, and between approximately 0 mg and approximately 1000 mg of phosphatidylinositol, wherein at least one component in said composition is present in an amount greater than [0]500 mg.

13. (Twice Amended) The composition of claim 4 wherein said herbal antioxidant comprises a daily dosage of between approximately 0 mg and approximately 7 mg of barberry, between approximately 0 mg and approximately 70 mg of bilberry proanthocyanidins, between approximately 0 mg and approximately 150 mg of lemon bioflavinoids, between approximately 0 mg and approximately 150 mg of lime bioflavinoids, between approximately 0 mg and approximately 150 mg of orange bioflavinoids, between approximately 0 mg and approximately 1000 mg of curcuma, between approximately 0 mg and approximately 2 mg of garlic bioflavinoids, between approximately 0 mg and approximately 180 mg of [ginko]gingko biloba, between approximately 0 mg and approximately 2000 mg of ginseng, between approximately 0 mg and approximately 100 mg of gotu kola, between approximately 0 mg and approximately 1000 mg of grape seed proanthocyanidins, between approximately 0 mg and approximately 1000 mg of red apple quercetin, between approximately 0 mg and approximately 1000 mg of red onion quercetin, and between approximately 0 mg and approximately 400 mg of Siberian ginseng, wherein at least one component in said composition is present in an amount greater than [0] 500 mg.